

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.: 10/561,529
Confirmation No.: 9788
First-Named Inventor: Fabrizio Samaritani
Filing Date: December 20, 2005
Group Art Unit: 1615
Examiner: Lorraine Spector
Attorney Docket No.: 7541-5
Title: FREEZE-DRIED FSH/LH FORMULATIONS

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

1. List of All Patents, Publications, U.S. Applications, or Other Information

Pursuant to the provisions of 37 CFR 1.56, 1.97, and 1.98, Applicant requests consideration of the references listed on the attached PTO/SB/08 form(s) (commonly referred to as a PTO-1449 form) and/or the additional information identified below.

2. Enclosed Legible Copies

2a. A legible copy of each foreign patent document and publication listed on the PTO/SB/08 form is enclosed,

☐ i. except, a copy is not provided for each reference previously cited by or submitted to the Patent Office in prior U.S. Patent Application Serial No. _____, filed _____ from which the present application claims priority under 35 U.S.C. §120.

☐ ii. except, a copy is not provided for each cumulative reference and enclosed reference identified below:

☐ 2b. A copy of the specification and drawings for each cited unpublished U.S. application.

- ☐ 2c. A copy of a Search Report or Written Opinion from a foreign patent office is also enclosed.
- ☐ 2d. Consideration of the enclosed additional and/or below discussed information is requested.

3. Concise Explanation of Relevance for Non-English Language Information

For each non-English language reference listed on the attached SB/08 form(s), reference is made to:

- ☐ 3a. an English language translation submitted herewith,
- ☐ 3b. foreign patent office Search Report (in the English language) submitted herewith,
- ☐ 3c. an English language translation of a foreign patent office Search Report submitted herewith,
- ☐ 3d. the concise explanation contained in the present application at page(s) ____,
- ☐ 3e. the concise explanation set forth in the attached English language abstract,
- ☐ 3f. a copy of a related patent publication (in the English language) cited herewith,

Foreign Patent Document	Corresponding English Language Patent Document

- ☐ 3g. the following concise explanation: _____.

4. Time for Filing

- ☒ 4a. This Information Disclosure Statement is submitted:
- ☐ i. for U.S. national applications or national stage PCT applications (not including CPAs and RCEs), within 3 months of filing or entry into national stage; or
- ☒ ii. for U.S. national applications, national stage PCT applications, CPAs or RCEs, before the first Office Action on the merits,

and thus no certification and/or fee is required.

- ☐ 4b. This information Disclosure Statement is submitted after three months from the filing date and after the first Office Action on the merits, but prior to the mailing date of a final Office Action or Notice of Allowance, and thus:

- ☐ i. the statement specified in 37 CFR §1.97(e) is provided below, or
- ☐ ii. a fee of \$_____ (set forth in 37 CFR §1.17(p)) is enclosed.
- ☐ 4c. This Information Disclosure Statement is submitted after the mailing date of a final Office Action or Notice of Allowance and prior to payment of the issue fee, and thus:
 - ☐ i. the statement specified in 37 CFR §1.97(e) is provided below, and a fee of \$_____ (set forth in 37 CFR §1.17(p)) is enclosed, or
 - ☐ ii. a Request for Continued Examination (RCE) and fee of 37 CFR §1.17(e) has been filed.
- ☐ 4d. This Information Disclosure Statement is submitted after payment of the issue fee, and thus:
 - i. a Petition to Withdraw from Issue pursuant to 37 CFR §1.313(c)(2) has been filed, and
 - ii. a Request for Continued Examination (RCE) and fee of 37 CFR §1.17(e) has been filed.

5. Certification- Statement Under 37 CFR 1.97(e)

- ☐ 5a. It is hereby certified that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- ☐ 5b. A copy of a dated communication from a foreign patent office which clearly shows the statement is being submitted within three (3) months of the date on the communication is enclosed.
- ☐ 5c. It is hereby certified that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

The filing of this Information Disclosure Statement shall not be construed as an admission that the information cited is, or is considered to be, material to patentability as defined in §1.56(b). It is believed that no additional fees are required. Should any other fee be required, however, please charge such fee to Deposit Account No. 23-3030, but not to include any payment of issue fees.

Respectfully submitted,

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